510(k) Summary

APR - 8 2011

Company: Ethicon Endo-Surgery, LLC
475 Calle C
Guaynabo, PR 00969

Contact: Dennis Hahn, RAC
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Date Prepared: December 16, 2010

Device Name: Reusable PPH Circular Stapler, Disposable Reload & Accessory Set

Common or Usual Name: Circular Stapler

Classification Name: Staple, Implantable

Predicate Device: PROXIMATE® PPH Hemorrhoidal Circular Stapler and Accessories (cleared under K051301)

Device Description: The Reusable PPH Circular Stapler, Disposable Reload & Accessory Set consists of a reusable circular stapler handle, a disposable reload (containing the anvil, knife, washer, and staples), and accessory set (consisting of the circular anal dilator, purse-string anoscope, anal introducer, and suture threader).

Indications for Use: The Reusable PPH Circular Stapler, Disposable Reload & Accessory Set has application throughout the anal canal to perform surgical treatment of hemorrhoidal disease.

Contraindications for use:

- Do not use where the combined compressed tissue thickness is less than 0.75 mm or greater than 1.5 mm, or where the internal diameter of the rectum will not accommodate the instrument and accessories. If the instrument is used on tissue less than 0.75mm or greater than 1.5 mm in thickness, an inadequate mucosal repair and inadequate hemostasis could result.
- Do not use the instrument on ischemic or necrotic tissue.
- Do not use the instrument for full rectal wall thickness resection.
- Do not use the instrument for the Stapled Transanal Rectal Resection (STARR).

Technological Characteristics: The Reusable PPH Circular Stapler, Disposable Reload & Accessory Set consists of three components: the reusable handle, the disposable reload, and the accessory set. The handle can be used for 200 applications. An adjustable knob on the handle adjusts the device for use on compressed tissue from 0.75 mm to 1.5 mm. The reload, which is designed for a single use, is made up of an anvil head with a diameter of 32.5 mm and two staggered rows of staples. Contained within the same sterile packaging as the reload, the disposable accessory set consists of a circular anal dilator, purse-string anoscope, anal introducer, and suture threader.

Performance Data: Bench testing was conducted to demonstrate and verify the performance of the disposable reload and the reusable handle after 200 simulated uses. Test results demonstrated the bench testing acceptance criteria were met.

Animal (tissue) testing was conducted to evaluate the pressure tolerance of an anastomotic stoma created in porcine colon. Testing results demonstrated that staple lines created by the stapler device met the leak pressure acceptance criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ethicon Endo-Surgery, LLC
% Ethicon Endo-Surgery, Inc.
Mr. Dennis Hahn, RAC
4545 Creek Road
Cincinnati, Ohio 45242

APR - 8 2011

Re: K103672
Trade/Device Name: Reusable PPH Circular Stapler, Disposable Reload & Accessory Set
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: II
Product Code: GDW
Dated: April 6, 2011
Received: April 7, 2011

Dear Mr. Hahn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K103672

Device Name: **Reusable PPH Circular Stapler, Disposable Reload & Accessory Set**

Indications for Use: The Reusable PPH Circular Stapler, Disposable Reload & Accessory Set has application throughout the anal canal to perform surgical treatment of hemorrhoidal disease.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103672